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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,033	11/21/2001	Stephen J. Chudzik	9896.129.3.1.1	9835

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EXAMINER

MICHENER, JENNIFER KOLB

ART UNIT	PAPER NUMBER
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1762

DATE MAILED: 12/03/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/989,033

Applicant(s)

CHUDZIK ET AL.

Examiner

Jennifer Kolb Michener

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 31-41 is/are pending in the application.
- 4a) Of the above claim(s) 41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group I, claims 31-40 in Paper No. 5 is acknowledged. The traversal is on the ground(s) that there is no additional search or burden of examining the method of using the coated device in claim 41 with the method of coating. This is not found persuasive because the method of implanting the coated device in claim 41 is based on the use of canceled device claim 21. The method of coating the device is unrelated to the method of implanting a medical device in vivo. Additionally, the method of implanting the device would require further search for the limitations claimed in claim 41 such as the degrees of flexion and expansion and method of placement and time within the human body. The art for a medical device and its method of use in the body is different than for methods of coating. The searches are different. And different issues during prosecution will arise between the two inventions.

The requirement is still deemed proper and is therefore made FINAL.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 31-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The elected independent method claim refers to the combination of claim 21 and the composition of claim 1. An independent claim may not depend on another claim.

Additionally, claims 1 and 21 have been canceled and a claim cannot depend from a canceled claim.

For the purposes of expediting prosecution only, the limitations of canceled claims 1 and 21 have been read into claim 31 for examination purposes. Therefore claim 31 has been read as: A method of preparing a coated medical device, the method comprising the steps of: providing a composition comprising a bioactive agent with a first polymer and a second polymer, wherein the first polymer is poly(alkyl)(meth)acrylate and the second polymer is poly(ethylene-co-vinyl acetate), and applying the composition to the medical device.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 31-34, 36, and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by Whitbourne et al. (6,110,483).

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Regarding claims 31 and 36, Whitbourne et al. teaches a method of coating a medical device with a bioactive coating in a plurality or combination of stabilizing polymers, such as polybutylmethacrylate and polyethylene-co-vinyl acetate (abstract; col. 2, lines 21, 35, and 55-67; col. 4, lines 13 and 64; col. 6, line 26; claim 1).

Regarding claim 32, Whitbourne teaches dipping or spraying (col. 7, line 21).

Regarding claim 33, Whitbourne teaches the use of the polymer composition in a solvent which is evaporated during drying, thus "curing" the composition (col. 7, line 25).

Regarding claim 34, Whitbourne teaches coating a stent (col. 5, line 62), which undergoes flexion and/or expansion when used in the body.

Regarding claim 38, Whitbourne teaches the use of the active agent at 0.01-20% by weight, lying within the range claimed by Applicant (col. 7, line 56).

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 35, 37, and 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitbourne et al.

Whitbourne teaches that which is disclosed above, but fail to teach some of the ranges claimed by Applicant.

Regarding claim 35, Whitbourne teaches the polybutylmethacrylate, which has a chain length of 4 carbons and the polyethylene-co-vinylacetate claimed by Applicant, but fails to teach the vinyl acetate concentration. It is Examiner's position however, that selection of a polyethylene and vinylacetate copolymer with a specific concentration of vinylacetate would have been within the skill of an ordinary skill in the art. Whitbourne teaches the necessity of crosslinkability of his polymer coatings and thus, selection of a concentration of the various reactive units of the copolymer would allow optimization of crosslinking in the coating.

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It is well settled that determination of optimum values of cause effective variables such as these process parameters is within the skill of one practicing in the art. *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Regarding claim 37, Whitbourne's polymer combination is preferably used at a concentration of 0.01-30% by weight, overlapping the range claimed by Applicant (col. 7, line 45).

Overlapping ranges are *prima facie* evidence of obviousness. It would have been obvious to one having ordinary skill in the art to have selected the portion of Whitbourne's range that corresponds to the claimed range. *In re Malagari*, 184 USPQ 549 (CCPA 1974).

Regarding claims 39-40, Whitbourne teaches a coating thickness of 2-100 microns, overlapping the range claimed by Applicant, however he fails to teach the concentration of bioactive agent per unit area of the medical device. Concentration of drug per unit area is a "dosage". It is Examiner's position that it is within the skill of an ordinary artisan to select the proper dosage of the bioactive agent depending on the type of agent used, the type of disease being treated, and the type of device being used for treatment. Determination of optimum variables is within the skill of an ordinary artisan for those reasons outlined above.

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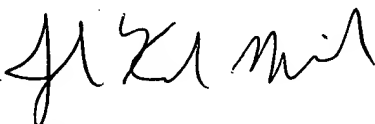
***Conclusion***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lentz 2002/0133183 teaches coating stents with the polymers of Applicant.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kolb Michener whose telephone number is 703-306-5462. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 703-308-2333. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



Jennifer Kolb Michener  
Patent Examiner  
Technology Center 1700  
11/26/2003